

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/GB 03/02936

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01N33/564 G01N33/569

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 26248 A (ISIS INNOVATION ;LALVANI AJIT (GB); PATHAN ANSAR AHMED (GB)) 11 May 2000 (2000-05-11)	1-5, 7-10,12, 14-23, 27,50, 51,53, 57-68, 71,72, 92,93
Y	page 3, line 1-13; claims 1-22; examples 2,3 --- -/--	24-26, 29-47, 54-56, 74-89

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

G document member of the same patent family

Date of the actual completion of the international search

8 January 2004

Date of mailing of the international search report

20/01/2004

Name and mailing address of the ISA

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PCT/GB 03/02936

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>PATHAN A A ET AL: "DIRECT EX VIVO ANALYSIS OF ANTIGEN-SPECIFIC IFN-GAMMA-SECRETING CD4 T CELLS IN MYCOBACTERIUM TUBERCULOSIS-INFECTED INDIVIDUALS: ASSOCIATIONS WITH CLINICAL DISEASE STATE AND EFFECT OF TREATMENT" JOURNAL OF IMMUNOLOGY, THE WILLIAMS AND WILKINS CO. BALTIMORE, US, vol. 167, no. 9, 1 November 2001 (2001-11-01), pages 5217-5225, XP001093768 ISSN: 0022-1767 the whole document</p>	<p>24-26, 29-47, 54-56</p>
Y	<p>LALVANI A ET AL: "Enhanced contact tracing and spatial tracking of Mycobacterium tuberculosis infection by enumeration of antigen-specific T cells" LANCET THE, LANCET LIMITED. LONDON, GB, vol. 357, no. 9273, 23 June 2001 (2001-06-23), pages 2017-2021, XP004247721 ISSN: 0140-6736 abstract</p>	<p>74-89</p>
A	<p>WO 01 04151 A (STATENS SERUMINSTITUT ;ANDERSEN PETER (DK); SKJOET RIKKE (DK)) 18 January 2001 (2001-01-18) the whole document</p>	<p>1-94</p>
P,X	<p>WO 02 054072 A (ISIS INNOVATION ;LALVANI AJIT (GB)) 11 July 2002 (2002-07-11) the whole document</p>	<p>1-5, 7-10, 12-20, 22-27, 29-40, 42-49, 51-54, 57-72, 74,77, 79-82, 84-93</p>

INTERNATIONAL SEARCH REPORT

In International application No.
PCT/GB 03/02936

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 20-21, 24, 26, 29-50, 53-57, 59-70, 74-78 and 80-91 include diagnostic/therapy methods involving the treatment of the human/animal body covered by the provisions of Rule 67.1 (iv) PCT.
2. ☒ Claims Nos.: 22-25, 27-28, 50-51, 71-73, 92-94
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

Continuation of Box I.2

Claims Nos.: 22-25, 27-28, 50-51, 71-73, 92-94

Present claims 22-25, 27-28, 50-51, 71-73 and 92-94 relate to an extremely large number of possible products which may be obtained from apparently any pathogen. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the products claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to peptide/antigen products obtained from *Mycobacterium tuberculosis*.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-94

diagnostic methods and kits

1.1. Claims: 1-28

methods of diagnosis/therapy in which T-cells recognize proteins derived from a pathogen and having at least 30 amino acids to a greater extent than one or more peptide epitope from the pathogen agent, and products and kits thereof.

1.2. Claims: 29-52

methods of diagnosis/therapy in which T-cells recognize antigens derived from a pathogen at a first and a second time point after exposure to the pathogen, and products and kits thereof.

1.3. Claims: 53-94

methods of diagnosis/therapy in which an increased level of T-cells recognize mycobacterial antigens, and products and kits thereof.

The present application lacks unity (Rule 13.1 PCT) because the above mentioned groups of inventions do not appear to be linked by a common single novel and inventive concept within the sense of Rule 13.2 PCT.

Please note that all inventions mentioned under item 1, although not necessarily linked by a common inventive concept, could be searched without effort justifying an additional fee.

INTERNATIONAL SEARCH REPORT

Intern 31 Application No

PCT/GB 03/02936

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0026248	A	11-05-2000	AU 6480999 A	22-05-2000
			BR 9915055 A	07-08-2001
			CA 2348475 A1	11-05-2000
			CN 1350546 T	22-05-2002
			EP 1144447 A2	17-10-2001
			WO 0026248 A2	11-05-2000
			JP 2002532064 T	02-10-2002
			ZA 200103356 A	24-01-2002
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			CA 2378763 A1	18-01-2001
			WO 0104151 A2	18-01-2001
			EP 1200466 A2	02-05-2002
			JP 2003510018 T	18-03-2003
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			WO 02054072 A2	11-07-2002